ORIGINAL

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BY FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: **Purdue Pharma L.P.**
Petition for Stay of Action
Oxycodone HCl Controlled-Release Tablets
Docket No. 2004P-0006

Endo Pharmaceuticals Inc. ("Endo" or the "company"), holder of a tentative approval letter for ANDA 75-923 for Oxycodone Hydrochloride (HCl) Controlled-Release Tablets 10 mg, 20 mg, 40 mg and 80 mg ("controlled-release oxycodone"), submits the following comments in response to the above-identified Petition for Stay of Action ("Petition"), which requests the Food and Drug Administration ("FDA" or the "Agency") to stay final approval of all Abbreviated New Drug Applications ("ANDAs") for such drug products, including Endo's application, "unless and until the products covered by those ANDAs are the subject of appropriate risk

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management programs ("RMPs") consistent with the risk management program for OxyContin."[1]

As described more fully below, the stay requested (i) is unwarranted and unnecessary to protect the public health; (ii) conflicts with the goals of the Hatch-Waxman amendments; (iii) would be bad policy; and (iv) in any event, would violate the clear and unambiguous language of the Food, Drug and Cosmetic Act ("FDCA" or the "Act").

I. INTRODUCTION

Endo is a leading manufacturer and distributor of opioid analgesic drug products for the management of moderate to severe pain in patients suffering from a variety of disease conditions. The company's controlled-substance products include such long-standing products as Percocet®, Percodan®, Endocet® and Endodan®, as well as controlled-release morphine sulfate, a generic formulation of Purdue Pharma L.P.'s MSContin®, a controlled-release opioid. Unlike most generic manufacturers, Endo also researches, develops, markets and distributes branded controlled-substance products. As a pharmaceutical company focused on the improvement of pain management, Endo feels a strong responsibility to improve the care of pain patients while at the same time safeguarding against potential misuse of its controlled-substance products. Endo currently has in place numerous risk management measures, as described more fully below. In fact, Endo is developing one of the most encompassing education programs in the industry with respect to the proper use and avoidance of abuse of opioid analgesics.

Over the past two years, FDA has begun to analyze the feasibility of applying risk management measures, in addition to current labeling requirements to augment existing measures and regulatory requirements in the prevention of drug misuse, abuse and diversion.

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[1] Petition for Stay of Action at 1 (submitted to FDA by Purdue Pharma on January 6, 2004).

More recently, FDA has indicated that risk management programs are an aspect in the Agency's consideration of approval of controlled-release opioid drugs. While the FDA has not issued any rule or guidance indicating that an approved RMP is required for approval of generic drug products, Endo understands the role of a voluntary RMP with respect to controlled-release opioid analgesics in light of the well-documented instances of abuse and diversion of such products, particularly with respect to the reference listed drug (OxyContin®). Consistent with this understanding, Endo is committed to working with the Agency to enhance the company's current risk management measures with a more formal RMP, which would aim to minimize abuse, misuse and diversion through appropriate drug labeling, tight controls on distribution, proactive pharmacovigilance and education. As will become clear below, Endo believes this to be appropriate for post-final approval.

Endo expects that its RMP will take into account somewhat different problems from those encountered with the innovator product. It is critical to understand that Endo's controlled-release oxycodone formulation is an AB-rated generic drug; as such, the applicable customers are retailers and wholesalers, and not physicians. Thus, Endo's controlled-release oxycodone sales and marketing activity will be limited to contracting with and supporting these trade and institutional companies and organizations, rather than marketing directly to physicians. For these reasons, such abuse or diversion as may have occurred from the promotion of OxyContin® to physicians by Purdue Pharma L.P. ("Purdue") will not need to be a focus of Endo's RMP.

Endo's existing risk management measures will be applied to controlled-release oxycodone at the time of launch and can be further tailored to fit the needs particular to this generic drug to protect against improper use, abuse and diversion. Endo's existing risk management measures, which would likely be incorporated into a RMP, include the following

multiple components: (1) product labeling; (2) tight oversight of the distribution chain (in which Endo has particular experience and already does oversee as a result of its distribution of its existing controlled-substance analgesics); (3) no drug sales representative activities or physician promotion; (4) proactive surveillance methods (again, in which Endo has particular experience and already engages in as a result of its distribution of its existing controlled-substances); (5) responsive interventions; and (6) continued close working relationships with FDA and DEA. In addition, though not specific to its controlled-release oxycodone product, Endo has well-developed educational initiatives in place and additional initiatives planned regarding the proper prescribing and clinical use of opioid analgesics as a class. These educational initiatives will be a valuable component of Endo's RMP because they will have a direct impact on appropriate use of the drug. Finally, Endo is at the forefront of development and validation of new clinical tools designed to assist physicians in assessing a patient's opioid abuse potential. Thus, Endo is confident that it will be able to develop expeditiously following final approval a comprehensive RMP that will enhance its existing strong measures and meet FDA's criteria. The public health will be well-protected without staying the approval of Endo's ANDA for controlled-release oxycodone as requested by Purdue Pharma L.P. ("Purdue") in its January 6, 2004 Petition.

Purdue's request for stay is entirely inconsistent with the policies underlying ANDAs and FDA's previously stated rationale for considering RMPs. Purdue's contention of harm to the public (and the basis it gives for harm to itself) is a fig-leaf that thinly disguises its true motivation: a blatant attempt to disrupt FDA's processes and further extend a monopoly that a federal court has decided was improperly extended in the first place through Purdue's inequitable conduct before a U.S. governmental agency, the Patent Office. The timing of Purdue's attempt -- the very next day after its patents were held invalid and on the eve of final approval of a

competitor - - is an "in your face" gauntlet thrown not only at FDA and potential competition but also at the public's cry for low cost pharmaceuticals.

Purdue's efforts to block Endo's imminent approval by cynical manipulation of FDA's procedures and Purdue's lack of good faith cannot be sanctioned by the Agency. To do so would severely compromise the integrity of the Agency's processes. The Petition must and should be denied.

II. GRANTING PURDUE A STAY WOULD BE INCONSISTENT WITH PUBLIC POLICY

Congress enacted the Hatch-Waxman Act principally to create a more expeditious and less costly regulatory process for FDA pre-market approval of generic versions of previously approved brand-name drugs.[2] This process enables generic formulations "to be marketed more cheaply and quickly."[3] Congress recently amended these provisions, in large part to curb abuses by pioneers seeking to extend this monopoly beyond Congress's intent.[4] Yet, a few weeks after this congressional enactment, Purdue has the temerity to come to FDA, wrapped in a thinly-veiled guise of public policy, seeking to "innovate" with a new delaying tactic.

To accomplish its goals in the Hatch-Waxman amendments, Congress set out the exact information it wanted an ANDA to contain. FDA was given the somewhat unusual, sharp and clear directive that the Agency could "not require that an abbreviated application contain

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[2] H.R. Rep. No. 98-857, pt. 1, at 14 (1984) *reprinted in* 1984 U.S.C.C.A.N. 2647.

[3] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

[4] *See* Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No.108-173 (117 Stat. 2066) §§ 1101-1103, 1111, 1117 (2003); *see also* 148 Cong. Rec. S7565 (daily ed. July 30, 2002) (statement of Sen. Hatch) ("I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition.").

information in addition to [eight specifically enumerated items listed in the statute]."[5] Yet, Purdue asks FDA to do just that -- to require additional information in Endo's ANDA. It wants more information in order, it says, to protect the public interest.

However, the protection gained from what Purdue would have FDA require is illusory. Giving in to Purdue's desperate attempt would thwart the Congressional policy behind Hatch-Waxman noted above, while actually impeding FDA's goal of preventing diversion and abuse -- the very policy Purdue claims requiring pre-approved RMPs would advance.

1. Endo's existing programs to manage the risk of abuse and diversion, together with Endo's commitment to work with FDA to further enhance its risk management measures post-final approval, will enhance public safety. Purdue's argument, when distilled to its essence, is that no one other than Purdue should be allowed to market controlled-release oxycodone because no other company is currently capable of distributing it in a manner that would not put the public safety at risk. Purdue's self-serving argument is dead wrong on the merits. As described above, Endo is a leader in the marketing and distribution of opioid analgesics, and Endo has existing comprehensive risk management measures in place.[6] Any launch by Endo will incorporate these risk management measures that, while not identical to Purdue's, will actually complement and enhance Purdue's RMP by providing additional tools for combating abuse and diversion. Thus, the public safety will be enhanced by Endo's launch of a generic, because the public will still receive the full benefit of Purdue's RMP while at the same time gaining the additional benefit of Endo's risk management measures. Endo's commitment to FDA to put a RMP in place post-final

[5] 21 U.S.C. § 355(j)(2)(A); *see infra* at 14.

[6] *Supra* at 2-4.

approval provides further assurances that the public health will benefit from the immediate approval of Endo's control-release oxycodone application.

2. Purdue's request would defeat the basic approach adopted in Hatch-Waxman to bring generic formulations to market cheaply. Congress's desire to allow generic products to enter the market without the same expense as a pioneer in obtaining an approval manifests itself most clearly in Congress's decision that ANDA applicants need only show bioequivalence to the reference-listed drug. To force ANDA applicants to repeat the same clinical trials required for approval of a New Drug Application (an "NDA") would, in essence, prevent any generic formulation from ever entering the market. Thus, Hatch-Waxman places this burden on the pioneer, and in exchange essentially grants the pioneer marketing exclusivity to recoup those costs. The benefit of the clinical trials redound to all. So, too, should RMPs. Purdue's argument that ANDA applicants be required to have something close to Purdue's RMP in place before approval is comparable to burdening an ANDA applicant with the expense of undertaking clinical trials -- an expense Congress sought to avoid to further its purpose of bringing competitive alternatives to the marketplace. Congress's express prohibition against FDA adding requirements to those set out in the statute[7] clearly aims at preventing just such a piling on of additions.

3. Purdue's suggestion would thwart the congressional purpose of bringing generic formulations to market quickly. RMPs are constantly changing. As Purdue admits, "FDA has reviewed and commented on multiple drafts of the RMP since August 2001."[8] Even after two years, Purdue's RMP remains subject to criticism and revision. Indeed, the RADARs aspect of

[7] 21 U.S.C. § 355(j)(2)(A).

[8] Petition at 5.

the OxyContin® RMP that Purdue vaunts in its Petition[9] was recently criticized by FDA as having flaws.[10] Despite this ongoing assessment of Purdue's OxyContin® RMP, Purdue continues to market OxyContin®. Yet, Purdue demands that FDA refrain from approving an ANDA for controlled-release oxycodone unless and until the applicant institutes an almost identical RMP to that which Purdue has been developing (and continues to develop) for over two years. This is particularly astounding when one bears in mind that Purdue has been developing, reassessing and correcting an RMP that it still apparently does not have right after the product that is the subject of the RMP, OxyContin®, has been on the market. It did not have a program in place at the time its NDA was approved, but would force that impediment onto others.

To some extent, this is inherent in the nature of the beast; development and implementation of RMPs for controlled-substances lend themselves to post-approval commitments. Most often, RMPs for pharmaceuticals are aimed at pharmacological risks -- even when used as indicated, Accutane® may cause birth defects in the event of fetal exposure through maternal use during pregnancy. With respect to controlled-release oxycodone, however, the risk is not pharmacological but behavioral. The risk of diversion and abuse is the result of an intervening behavioral pattern: persons seek to use the drug for illegal recreational purposes rather than for its intended use of pain management. This risk manifested itself only after approval. The proper tailoring of a full RMP for controlled-release oxycodone will benefit from at least some post-approval experience in how, if at all, the introduction of a generic affects this drug's abuse.

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[9] Petition at 4.

[10] Transcript of Sept. 10, 2003 Meeting of the Anesthetic and Life Support Drugs Advisory Committee at 169-172 (Presentation of Dr. Sharon Hertz, Team Leader, Division of Anesthetic, Critical Care and Addiction Drug Products), *available at* http://www.fda.gov/ohrms/dockets/ac/03/transcripts/3978T2.DOC; *see infra* at 9-10.

The exclusivity period conferred to Purdue under the Act is over. However, under Purdue's proposal, Endo and other ANDA applicants must refrain from marketing generic formulations of controlled-release oxycodone until after they have developed expensive RMPs that Purdue has had over two years to develop and implement. As a practical matter, Purdue's suggestion simply extends its now expiring period of exclusivity -- an exclusivity a federal court has concluded was obtained by Purdue's inequitable conduct before the Patent Office -- for so long as it takes Endo and other ANDA applicants to implement an RMP similar to Purdue's moving target plan -- possibly a two year or, perhaps endless, project.

Significantly, Purdue's simultaneous request that FDA approve its RMP as labeling would, if approved, authorize Purdue to extend its exclusivity by merely altering its RMP each time an ANDA applicant was close to finalizing its ANDA or RMP program. In essence, Purdue could create perpetual exclusivity by continually modifying its RMP and thereby obligating each ANDA applicant to modify its own program. The Hatch-Waxman Act simply does not allow innovators to unilaterally extend the exclusivity provision, and FDA should not participate in Purdue's blatant attempts to circumscribe the Act.

4. Purdue's moving target RMP suffers from deficiencies. The fact is that Purdue's RMP is a moving target which suffers from deficiencies that FDA has stated it is uncertain how to address.[11]

Forcing Endo or any other ANDA applicant to spend two years or more developing a RMP that is acceptable to FDA -- when even Purdue's still needs work -- before being allowed to begin marketing a controlled-release oxycodone product that meets all of the statutory and regulatory requirements for approval would unnecessarily and unreasonably delay entry of

[11] *Id.*

competitive drugs in direct contravention of Congress's intent, and in return for questionable gain.

That Purdue still does not, and for perhaps even understandable reasons cannot, have a final RMP firmly in place is telling. It means:

> (1) A duplicate or conforming RMP should certainly not be required pre-final approval from Endo or other generics;
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> (2) The public would benefit from additional approaches, with an effect that is far more likely to be additive than disruptive; and
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> (3) The science of RMPs for controlled-release oxycodone is still evolving and could take years to settle.

5. Requiring duplication as Purdue seeks would be wasteful. It makes little sense for a physician to receive an educational brochure from Purdue one day and an identical or conforming one from Endo the next, especially when Endo already has in place a well-developed educational program for its opioids. To require Endo to conform to Purdue's would be self-defeating and wasteful.

6. A requirement for an identical RMP would be inconsistent with FDA's own policies. FDA has expressly ruled that:

> Compliance by generic manufacturers with the essential elements of [a] risk management program is an issue distinct from approval of general versions of isotretinoin...Action can be taken to address these issues [adverse reactions] should they materialize, but their potential occurrence does not block the ability of duplicate producers to enter the marketplace. Thus, the possibility that one or more manufacturers of isotretinoin will fail to fully meet their risk management obligations is ***not*** an impediment to approval of their applications conditioned on full performance.[12]

[12] *See* Nov. 8, 2002 Letter from Janet Woodcock to Ellen J. Flannery, Docket No. 02P-0059/CP1 at 8 (emphasis added).

Thus, FDA has already expressly rejected Purdue's position that approval of Endo's ANDA should be stayed pending development and compliance with an RMP conforming to Purdue's OxyContin® RMP.

7. FDA has previously indicated that the decision about whether an RMP should be developed, submitted or implemented will occur on a case-by-case basis.[13] Purdue's request that FDA automatically obligate generic controlled-release oxycodone manufacturers to develop an RMP similar to Purdue's OxyContin® RMP as a prerequisite to approval of an ANDA is incompatible with FDA's policy of considering RMPs on a case-by-case basis. And, as noted above, even in the Accutane® situation, FDA made clear that a generic RMP need only "contain the same essential elements" as the innovator's RMP and "convey essentially the same important information" to the relevant population.[14] FDA stated that "if evidence shows that the risk management program of a particular manufacturer is inadequate with respect to the essential elements or is performing particularly worse than the programs of other manufacturers, we will address the particular manufacturer's deficiency."[15]

8. Granting Purdue's request for approval of its RMP as labeling would open the floodgates to constant delay of generic approvals. To permit Purdue to come in just before ANDA final approval and change its labeling or suddenly ask to incorporate its RMP into its labeling would set a terrible precedent. Thus would begin a never-ending series of changes to Purdue's RMP and/or its labeling as soon as Endo has caught up with the last change.

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[13] *See* "Concept Paper on Risk Management Programs," Presentation by Dr. Anne Trontell, Risk Management Working Group Chair, at slide 23 (April 10, 2003), *available at* http://www.fda.gov/cder/meeting/riskmanagement.htm; Risk Management Programs Concept Paper (Draft), at 4 (March 3, 2003), *available* at http://www.fda.gov/cder/meeting/groupIIfinal.pdf ("FDA anticipates that the decision to develop, submit, and implement an RMP will be made on a case-by-case basis.").

[14] *See* Nov. 8, 2002 Letter from Janet Woodcock to Ellen J. Flannery, Docket No. 02P-0059/CP1 at 2, 8.

[15] *Id.* at 8-9.

Purdue's timing speaks volumes. Purdue filed its Petition for Stay one day after its patents claiming controlled-release oxycodone were declared invalid.[16] Considering the length and detail in its Petition, Purdue obviously had prepared its Petition for Stay, with the accompanying labeling supplements, well in advance, but filed the Petition only after it lost its patent case.

Purdue amended its labeling of OxyContin® in 2001 to include a "black box" warning. At the same time, Purdue began developing its RMP. However, (a) Purdue did not seek to supplement its labeling to add information about its RMP until late December 2003, almost two-and-half years after first implementing its RMP and two weeks before the decision invalidating its patents; (b) it was not until after the decision of the federal court in New York that Purdue submitted its label supplements to add descriptions of its education programs; (c) it was not until after that decision that Purdue indicated its intent to seek approval of its RMP as labeling; and (d) that request has yet to be submitted. [17]

Purdue's eleventh hour timing of the supplements it offers here should sound a loud and clear alarm warning to the Agency that Purdue can be expected to do the same thing--over and over again. It would also encourage other manufacturers to begin using the same gimmick as they are about to face generic competition.

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[16] *Purdue Pharma L.P., et. al v. Endo Pharmaceuticals Inc., et al.*, 2004 WL 26523 (S.D.N.Y. Nos. 00 Civ. 2109, 01 Civ. 8177 (SHS), Jan. 5, 2004).

[17] The true nefarious purpose of Purdue's petition is evident in the contradictory position it takes regarding its RMP, portions of which it continues to maintain are proprietary, and yet which it argues all generics should be required to copy.

9. Immediate generic approval will result in decreased promotional activities for OxyContin®. Purdue has engaged in overzealous promotion of its product.[18] Immediate approval of controlled-release oxycodone should have the practical effect of decreasing any potential risk posed by the innovator's promotion of OxyContin®. Because of the high generic substitution rates which occur shortly after a generic product comes to market, promotion to doctors by the innovator company typically ceases because it is no longer economically efficient for those companies to encourage doctors to write a prescription for a drug that is most likely going to be filled by a competing company's generic.[19]

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For all of the above reasons, granting the stay sought by Purdue in this Petition would simply be bad public policy.

III. THE RELIEF REQUESTED IN THE PETITION FOR STAY VIOLATES THE FDCA

Purdue's demand that FDA stay final approval of Endo's ANDA for controlled-release oxycodone products until (1) FDA approves Purdue's sudden spate of labeling changes for the reference drug product and (2) Endo develops and implements an RMP fully consistent with that for the reference drug product violates the Federal Food Drug and Cosmetic Act. Congress has clearly defined and limited the criteria that may be considered in approving an ANDA. FDA has previously recognized and respected those limitations in connection with establishment and

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[18] *See* Warning Letter to Purdue Pharma L.P. dated January 17, 2003 from Thomas Abrams, Director, Division of Drug Marketing, Advertising and Communications, at page 3, stating that Purdue's promotional activities "suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use, is especially egregious and alarming in its potential impact on the public health."

[19] In fact, Purdue's President and Chief Executive Officer, Michael Friedman, has stated, "If sales of OxyContin® ... fall sufficiently, Purdue will ... have to reduce the size of its sales force...." *See* Declaration of Michael Friedman in Support of Purdue's *Ex Parte* Motion for Stay, at page 4, para. 12 (Jan. 12, 2004).

implementation of RMPs for generic products. To delay the final approval of any ANDA based on conveniently-timed proposals for label changes submitted by the reference drug product manufacturer or exact compliance with RMP conditions established by that manufacturer (some of which are maintained as confidential and proprietary by that manufacturer) would violate the FDCA.

Section 505(j)(2)(A) of the FDCA specifies the eight items that must be included in an abbreviated new drug application.[20] The statute requires information indicating the parallels between the new drug and the previously approved listed drug regarding conditions of use, active ingredients, dosage and route of administration, bioequivalency and labeling; and requires information on components, composition, methods of production, as well as product samples and specimens of labeling for both the listed and new drugs.[21] The ANDA application must also contain a certification as to any existing patent rights related to the drug, as well as information regarding any intended use not previously claimed in the application for the listed drug.[22] Most significantly, Congress explicitly instructed that FDA "may not require that an abbreviated application contain information in addition to" the items listed in § 505(j)(2)(A).[23]

Congress further mandated that FDA "shall approve" an ANDA application "unless" it fails to provide the information required by § 505(j)(2)(A) or if the information so provided indicates that the new drug has failed to satisfy one of the enumerated statutory requirements.[24]

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[20] 21 U.S.C. § 355(j)(2)(A).

[21] 21 U.S.C. §§ 355(j)(2)(A)(i) – (vi); 21 U.S.C. §§ 355(b)(1)(B) – (F).

[22] 21 U.S.C. §§ 355(j)(2)(A)(vii) – (viii).

[23] 21 U.S.C. § 355(j)(2)(A).

[24] 21 U.S.C. § 355(j)(4).

Eighteen months ago, FDA determined that Endo's application met each of the statutory criteria and granted Endo tentative approval of its ANDA pending resolution of the patent litigation initiated by Purdue or expiration of the 30-month stay triggered by that litigation.[25]

Nothing has changed since FDA's tentative approval of Endo's ANDA that is relevant to the statutory criteria for approval. Purdue appears to contend that its unilateral decision to incorporate its entire RMP into its labeling means that all ANDA approvals must be stayed until FDA determines whether Purdue's unilateral changes are appropriate. However, Congress has clearly commanded that ANDA approval be delayed only if "the information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling ***approved for the listed drug referred*** to in the application except for changes required . . . because the drug and the listed drug are produced or distributed by different manufacturers."[26] FDA cannot delay ANDA approval based on Purdue's last-minute papering of the Agency with label change proposals. Should FDA eventually approve Purdue's labeling changes, those changes can, if appropriate, be adopted -- in consultation with FDA and to the extent not due to the fact of distribution by different manufacturers -- by any approved ANDA holder then marketing products, as is the case with any other change to reference drug product labeling.

Nor does anything in Purdue's Petition support a finding that Endo's ANDA "is insufficient to show that each of the proposed conditions of use have been previously approved

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[25] *See* "Tentative Approval Letter for ANDA 75-923 (Oxycodone HCl Extended-Release Tablets)," Office of Generic Drugs, Food and Drug Administration (July 31, 2002).

[26] 21 U.S.C. § 355(j)(4)(G)(emphasis added).

for the listed drug referred to in the application."[27] To the extent that Purdue suggests that conformity to its own RMP is a condition of use necessary for ANDA approval, FDA has already rejected that contention. When in connection with the drug Accutane®, FDA was faced with a reference drug manufacturer attempting to delay ANDA approval by bootstrapping its RMP into the requirements for approval, FDA refused to grant relief that would delay that approval. FDA determined that its approval of the reference drug manufacturer's decision to include the RMP would not result in generic manufacturers being required to develop and implement their own RMPs that are identical to or as effective as the RMP of the pioneer drug manufacturer.[28] FDA indicated that generic manufacturers should have RMPs "that contain the same essential elements" as the RMP for the reference listed drug.[29] FDA also recognized that in a marketplace where drug substitution occurs freely, generic manufacturers should not be required to reproduce every element of the reference drug's RMP already in place, as adequate information would already be publicly available in order to address the public health concerns posed by the drug.[30]

FDA has determined that generic manufacturers should seek to implement their own programs that incorporate the "essential elements" of a reference listed drug's RMP, but has recognized that many of the components of such an RMP are specific to the reference listed drug's brand.[31] As noted above, Endo stands ready to work with FDA to finalize such a

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[27] 21 U.S.C. § 355(j)(4)(B).

[28] FDA Response to Citizen Petition by Hoffmann-LaRoche Inc., Docket No. 02P-0059/CP1 (November 8, 2002).

[29] *Id.* at 3.

[30] *Id.*

[31] FDA Response to Citizen Petition by Hoffmann-LaRoche Inc. at 4.

program, and has extensive experience and expertise in doing so. However, such a program is not a statutory requirement for ANDA approval. Purdue's attempt to unilaterally impose additional criteria on Endo's controlled-release oxycodone ANDA that FDA has already approved substantively is contrary to the FDCA and must be rejected.

CONCLUSION

The discussion above demonstrates that petitioner has failed to meet its burden for the stay to be granted. First, the timing of the Petition and the factors discussed above bespeak of the frivolousness of petitioner's case and petitioner's lack of good faith in its blatant attempt to frustrate and manipulate FDA's processes.

Second, petitioner's speculation about dilution of its RMP is just that--speculation with no meaningful support offered. The only injury Purdue may suffer is the loss of its ill-gotten monopoly extension. Indeed, by denying Purdue's Petition, FDA will not injure the public's health and safety but will, in fact, further it. The public will continue to receive the benefit of Purdue's RMP. Once Endo begins to sell its controlled-release oxycodone, the risk management measures it uses will complement Purdue's RMP and further enhance the public safety. In addition, Purdue's decreased promotion of OxyContin®, which will result from the introduction of generic competition, should further decrease the potential risk to the public health and safety.

Finally, petitioner has not demonstrated sound public policy grounds to support a stay. To the contrary, a stay would be bad public policy and would, furthermore, compromise the public health interest in the prompt availability of low-cost pharmaceuticals that is so important to so many.

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For the foregoing reasons, Endo respectfully urges FDA to deny Purdue's Petition for Stay of Action.

Respectfully submitted,

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